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Development Document for Final Best Conventional Technology Effluent Limitations Guidelines for the Pharmaceutical Manufacturing Point Source Category

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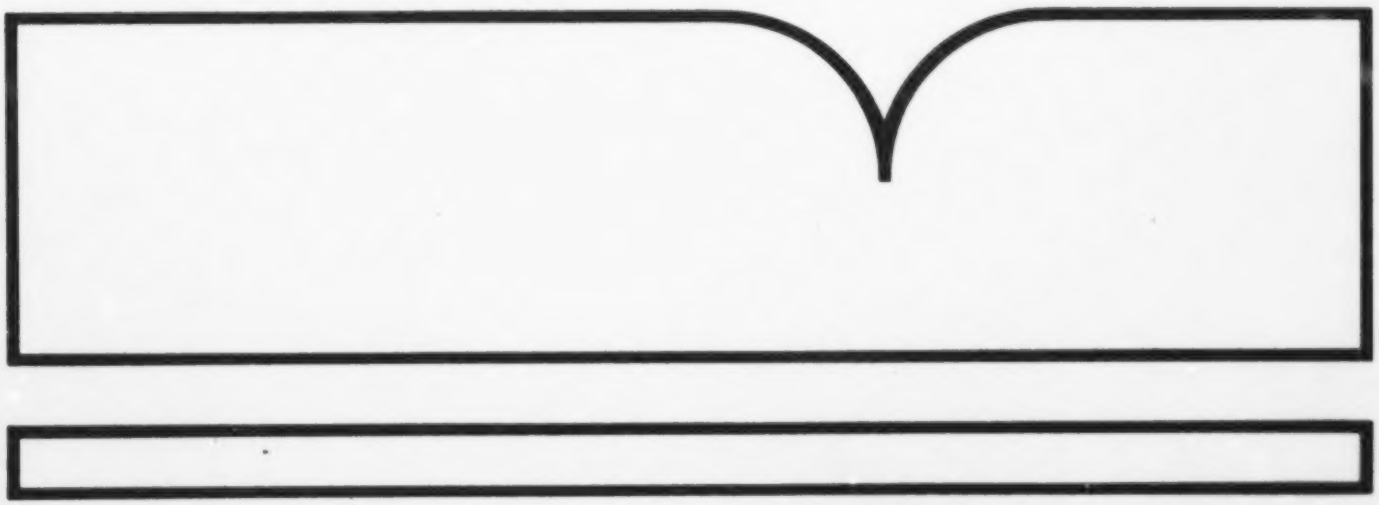

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This document presents the technical retionale for best conventional technology (BCT) effluent limitations guidelines for the pharmaceutical manufacturing point source category as required by the Clean Water Act of 1977 (P.L. 95-217, "the Act"). This document descibes the technologies considered as the bases for BCT limitations.

Section II of this document summarizes the rulemaking process. Sections III through V describe the technical data and engineering analyses used to develop the regulatory technology options. The costs and removals associated with each technology option for each plant and the application of the BCT cost test methodology are presented in Section VI. BCT limitations bases on the best conventional pollutant control technology are to be achieved by existing direct descharging facilities.

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DEVELOPMENT DOCUMENT

FOR

FINAL BEST CONVENTIONAL TECHNOLOGY

EFFLUENT LIMITATIONS GUIDELINES

FOR THE

PHARMACEUTICAL MANUFACTURING

POINT SOURCE CATEGORY

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SECTION I

EXECUTIVE SUMMARY

SUMMARY

This document presents the technical rationale for best conventional technology (BCT) effluent limitations guidelines for the pharmaceutical manufacturing point source category as required by the Clean Water Act of 1977 (P.L. 95-217, "the Act"). This document describes the technologies considered as the bases for BCT limitations.

EPA developed these limitations and standards after undertaking a complex program utilizing industry data obtained under authority of Section 308 of the Act, supplemented by additional data collection programs for selected portions of the industry.

Plants in the pharmaceutical manufacturing point source category produce biological products, medicinal chemicals, botanical products and pharmaceutical products covered by Standard Industrial Classification Code (SIC) Numbers 2831, 2833, and 2834, and other commodities described within this report.

The industry is characterized by diversity of product, process, plant size, and process stream complexity. Subcategories based on process characteristics were defined for purposes of technical evaluation. These subcategories were found to be appropriate for regulatory purposes.

Section II of this document summarizes the rulemaking process. Sections III through V describe the technical data and engineering analyses used to develop the regulatory technology options. The costs and removals associated with each technology option for each plant and the application of the BCT cost test methodology are presented in Section VI. BCT limitations based on the best conventional pollutant control technology are to be achieved by existing direct discharging facilities.

CONCLUSIONS

The Environmental Protection Agency (EPA) is finalizing regulations that would limit the discharge of five-day biochemical oxygen demand (BOD_5) and total suspended solids (TSS) into waters of the United States by existing sources in four subcategories of the pharmaceutical manufacturing point source category. This document addresses best conventional technology (BCT) limitations for conventional pollutants required under the Clean Water Act.

BEST CONVENTIONAL POLLUTANT LIMITATIONS (BCT)

The technology basis of final BCT for the control of BOD_5 and TSS is biological treatment (i.e., biological treatment considered as the basis of best practicable control technology currently available (BPT)). Final BCT are shown in Table I-1.

TABLE I-1

FINAL BCT LIMITATIONS FOR THE
PHARMACEUTICAL MANUFACTURING CATEGORY

Subcategory	BOD_5 30-Day Maximum Average	TSS 30-Day Maximum Average	pH
A	0.10 x long-term average raw waste concentration x 3 (variability factor)	1.7 x BOD_5 30-day maximum average limitation	6.0-9.0 units at all times
B	0.10 x long-term average raw waste concentration x 3 (variability factor) or 45 mg/l, whichever is higher	1.7 x BOD_5 30-day maximum average limitation	6.0-9.0 units at all times
C	0.10 x long-term average raw waste concentration x 3 (variability factor)	1.7 x BOD_5 30-day maximum average limitation	6.0-9.0 units at all times
D	0.10 x long-term average raw waste concentration x 3 (variability factor) or 45 mg/l, whichever is higher	1.7 x BOD_5 30-day maximum average limitation	6.0-9.0 units at all times

SECTION II

INTRODUCTION

PURPOSE AND AUTHORITY

The Federal Water Pollution Control Act Amendments of 1972 established a comprehensive program to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters." (Section 101(a)). To implement the Act, EPA was required to issue effluent limitations guidelines, pretreatment standards, and new source performance standards for industrial dischargers.

EPA promulgated effluent limitations guidelines based on Best Practicable Technology and Best Available Technology, New Source Performance Standards and New Source Performance Standards based on Best Available Demonstrated Technology as well as pretreatment standards for existing and new sources for the pharmaceutical manufacturing category on October 27, 1983 at 48 FR 49808.

The 1977 amendments to the Clean Water Act added Section 301(b)(2)(E) establishing "best conventional pollutant control technology" (BCT) for discharges of conventional pollutants from existing industrial point sources. Conventional pollutants are those defined in Section 304(a)(4) [biological oxygen demanding (BOD_5), total suspended solids (TSS), fecal coliform, and pH], and any additional pollutants defined by the Administrator as "conventional" (oil and grease, 44 FR 44501, July 30, 1979).

BCT is not an additional limitation but replaces BAT for the control of conventional pollutants. In addition to other factors specified in section 304(b)(4)(b), the Act requires that BCT limitations be assessed in light of a two part "cost reasonableness" test, American Paper Institute v. EPA, 660 F.2d 954 (4th Cir. 1981). The first test compares the cost for private industry to reduce its conventional pollutants with the costs to publicly owned treatment works for similar levels of reduction in their discharge of these pollutants. The second test examines the cost effectiveness of additional treatment beyond BPT. EPA must find that limitations more stringent than BPT are "reasonable" under both tests before establishing them as BCT. If they are not found "reasonable" then BCT will be established as equal to BPT. In no case may BCT be less stringent than BPT.

EPA published its methodology for carrying out the BCT analysis on August 24, 1979 (44 FR 50732). In the case mentioned above, the Court of Appeals ordered EPA to correct data errors underlying EPA's calculation of the first test, and to apply the second test (EPA had argued that a second test was not required). The Agency proposed a revised methodology for the general development of BCT limitations on October 29, 1982 (47 FR 49176)

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and an additional Notice of Data Availability on September 20, 1984 (49 FR 37046). On November 26, 1982, EPA proposed BCT limitations for the pharmaceutical point source category based on the proposed BCT methodology. The BCT methodology has recently been published in final form. (See 51 FR 24974 on July 9, 1986). Final BCT limitations for the pharmaceutical manufacturing point source category have been developed based on this methodology and are the subject of this document.

EPA is promulgating this regulation under the authority of Sections 301, 304, 306, 308, and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendments of 1972, 33 U.S.C. 1251 et seq., as amended by the Clean Water Act of 1977, Public Law 95-217), also called the "Act."

SCOPE OF THIS RULEMAKING

On November 26, 1982, EPA proposed regulations applicable to the pharmaceutical manufacturing point source category (47 FR 53584). At that time, EPA (a) proposed to modify the existing BPT TSS effluent limitations for three subcategories (subcategory B--extraction products, subcategory D--mixing/compounding and formulation, and subcategory E--research), (b) proposed BPT TSS effluent limitations for two subcategories (subcategory A--fermentation products, and subcategory C--chemical synthesis products, (c) proposed to modify the existing BPT effluent limitations for BOD_5 and COD for subcategories A, B, C, and D, and E, (d) proposed BPT and BAT effluent limitations, NSPS, PSES, and PSNS for cyanide to apply uniformly to subcategories A, B, C, and D, (e) proposed BAT limitations and NSPS for chemical oxygen demand (COD) to apply uniformly to subcategories A, B, C, and D, (f) proposed BCT effluent limitations for BOD_5, TSS, and pH to apply uniformly to subcategories A, B, C, and D, and (g) proposed NSPS for BOD_5, TSS, and pH to apply uniformly to subcategories A, B, C, and D, based on the application of advanced biological treatment (i.e., biological treatment systems with longer detention times than those considered as the basis of effluent limitations reflecting the best practicable control technology currently available (BPT)).

In October of 1983, the Agency promulgated regulations covering most aspects of the November 1982 proposal. In brief, EPA finalized BPT effluent limitations for TSS for subcategories A and C and modified existing BPT BOD_5, COD, and TSS effluent limitations for subcategories B, D, and E. The Agency also established BPT and BAT effluent limitations guidelines, NSPS, PSES, and PSNS controlling cyanide discharges from pharmaceutical plants in subcategories A, B, C, and D. EPA has not promulgated final BAT effluent limitations and NSPS for COD because the Agency needs more information on the identity of the pollutants that contribute to COD and on applicable COD removal technologies. The Agency also did not address best conventional pollutant control technology (BCT) because the BCT methodology had not yet been issued.

However, a BCT methodology has recently been promulgated by EPA at 51 FR 24974 on July 9, 1986. The Agency has applied this methodology to two technology options for plants in the A and C and B and D subcategories. As a result, EPA is promulgating final BCT limitations for the A, B, C, and D subcategories of the pharmaceutical manufacturing category. This document provides technical support for the final BCT effluent limitations guidelines and has been developed after consideration of the public comments and newly acquired data.

The public comments considered and responded to by the Agency in this rulemaking were submitted in response to three Federal Register publications by the Agency which concerned pharmaceutical BCT limitations. Comments were initially received in response to the publication of proposed BCT limitations on November 26, 1982 at 47 FR 53584. The Agency also received comments on NSPS proposed on October 27, 1983 at 48 FR 49832 and on a notice of availability concerning new cost information to be used in the development of BCT limitations on March 9, 1984 at 49 FR 8697. The comments on the proposed NSPS have been considered in the context of BCT because the technology options considered as the basis for NSPS were identical to those considered as candidate BCT options. The Agency stated this in its March 9, 1984 notice.

SUMMARY OF METHODOLOGY

EPA's implementation of the Act required a complex development program, described in detail in the Proposed Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Point Source Category (U.S. EPA, November 1982) (1) First, EPA studied the pharmaceutical industry to determine the impact of raw material usage, final products manufactured, process equipment, size and age of manufacturing facilities, water use, and other factors on the level of conventional pollutants discharged from plants in this industry. This required the identification of raw waste and final effluent characteristics, including the sources and volumes of water used, the manufactuirng processes employed, and the sources of pollutants and wastewaters within the industry.

EPA then identified all subcategories for which BCT should be proposed and characterized the raw waste conventional pollutant discharges from plants in these subcategories. Next, EPA identified several distinct control and treatment technologies which are in use or capable of being used to control conventional pollutants in pharmaceutical industry wastewaters. The Agency compiled and analyzed historical and newly-generated data on effluent quality resulting from the application of these technologies. The long-term performance, operational limitations, and reliability of each of the treatment and control technologies were also identified. In addition, EPA considered the non-water quality environmental impacts of these

technologies, including impacts on air quality, solid waste generation, and energy requirements.

The Agency then estimated the costs for each control and treatment technology from unit cost curves developed by standard engineering analysis as applied to the specific pharmaceutical industry wastewater characteristics. EPA derived unit process costs from model plant characteristics (flow, pollutant raw waste loads) applied to each treatment process unit cost curve (i.e., primary clarification, activated sludge, filtration). These unit process costs were combined to yield the total installed equipment cost at each treatment level. Total capital costs were then derived from the installed equipment costs.

The Agency has also calculated the incremental pollutant removals for BOD_5 and TSS from BPT levels of treatment. These data as well as the incremental cost estimates were used in the application of the BCT cost test methodology in order to determine the technological basis of final BCT limitations. The methodology for estimating individual plant costs associated with each technology option and the calculation of pollutant removals associated with each option are discussed in section VI of this document.

Prior to applying the BCT cost test methodology, the Agency evaluated all comments received concerning the technology options as well as all other aspects of the proposed BCT limitations such as subcategorization and cost estimation. Responses to all comments on the proposed BCT limitations may be found in "Summary of Comments and Responses on the November 26, 1982 Proposed BCT Regulations, the October 27, 1983 Proposed NSPS Regulations, and the March 9, 1984 Notice of Availability for the Pharmaceutical Manufacturing Industry." Thereafter, EPA applied the BCT cost test methodology to four of five subcategories of the Pharmaceutical Industry (A, B, C, and D). The cost test was not applied to the fifth subcategory, pharmaceutical research, because production and wastewater generation from this subcategory are on an intermittent basis and thus the subcategory is outside the scope of effluent limitations guidelines development. As a result of the cost test application to four subcategories involving two technology options, EPA is promulgating final BCT limitations for BOD_5 and TSS equal to existing BPT limitations on this pollutant.

SECTION III

DESCRIPTION OF THE INDUSTRY

INTRODUCTION

Pharmaceutical plants manufacture biological products, medicinal chemicals, botanical products, and other pharmaceutical products. EPA identified 465 operating facilities involved in the manufacture of pharmaceutical products. Most of the pharmaceutical industry is located in the eastern half of the United States. The most prevalent manufacturing operation in the industry is the formulating, mixing, and compounding operation; batch-type production is the most common mode of manufacturing for this industry.

The wastewaters produced and discharged by the pharmaceutical industry are very diverse. Plant size, products, processes, and materials to which wastewater is exposed vary greatly. Additionally, the ratio of finished product to the quantity of raw materials, solvents, and other processing materials is generally very low. A detailed discussion of the pharmaceutical industry is included in Section III of the final development document and in Section III of the proposed development document.(1)(2)

SUBCATEGORIZATION

As described in Section II of the proposed NSPS document, the Agency is maintaining the original BPT subcategorization scheme, under which the pharmaceutical manufacturing industry was segmented into the following five subcategories:

Subcategory A: Fermentation Products
Subcategory B: Extraction Products
Subcategory C: Chemical Synthesis Products
Subcategory D: Mixing/Compounding and Formulation
Subcategory E: Research

A detailed description of the manufacturing processes and raw materials used in each of subcategories A, B, C, and D is presented in Sections III and IV of the proposed development document (1) and in the final development document (2). EPA did not propose BCT for the research subcategory because pharmaceutical research does not involve production, nor does it generate wastewater in appreciable quantities on a regular basis. Therefore, the Agency is not promulgating final BCT limitations for the research subcategory (E).

The Agency received no comments on its decision to maintain the original BPT subcategorization scheme. The rationale for maintaining the original subcategorization is discussed in

Section IV of the 1980 final development document.(2) Since the Agency believes that this scheme is the most reasonable regulatory scheme available, final BCT are being promulgated in accordance with this subcategorization scheme.

EXISTING END-OF-PIPE TREATMENT AT PHARMACEUTICAL PLANTS

Table III-1 presents information on the methods of wastewater discharge employed at the 465 pharmaceutical manufacturing plants in the Agency's data base. At 11 percent of the plants, wastewater is treated on-site in a treatment system operated by plant personnel and discharged directly to waters of the United States. At 60 percent of the pharmaceutical facilities, wastewater is discharged to a publicly owned treatment works (POTW). At 29 percent of the pharmaceutial plants, wastewater is not generated or all of the wastewater that is generated is not discharged to navigable waters.

Table III-2 presents information on the types of treatment currently in-place at direct discharging pharmaceutical plants. Seventy-five percent of the direct discharging plants in the industry utilize biological treatment, and 16 percent of the direct discharging plants employ filtration systems in addition to biological treatment.

TABLE III-1

SUMMARY OF METHOD OF DISCHARGE
AT PHARMACEUTICAL PLANTS

Method of Discharge	No. of Plants
Direct Dischargers	52
Indirect Dischargers	279
Zero Dischargers	134
Total Plants	465

Since proposal, it has been learned two direct discharging plants have become indirect and one plant is no longer manufacturing pharmaceuticals (see Table III-1 in the Proposed Development Document for comparison).

TABLE III-2

IN-PLACE TREATMENT TECHNOLOGY AT
DIRECT DISCHARGING PHARMACTEUTICAL PLANTS

Treatment Technology	No. of Plants
Biological Treatment	32
Biological Treatment Plus Filtration	8
Physical Chemical	3
Other	4
Unknown	1
Total Plants	48*

* Four direct discharging plants primarily produce products other than pharmaceuticals and, therefore, have not been included in the data base.

SECTION IV

WASTE CHARACTERIZATION

INTRODUCTION

The Agency conducted an extensive data gathering effort and developed qualitative and quantitative information on the characteristics of the wastewaters discharged by the pharmaceutical industry. This section summarizes available information on the characteristics of raw waste and final effluent discharges from direct discharging pharmaceutical plants. Only conventional pollutant data are presented in this document.

WASTE CHARACTERIZATION

Table IV-1 presents a summary of available raw waste and final effluent BOD_5 and TSS data for direct discharging pharmaceutical plants. This table is an updated version of the one that appeared in the proposed NSPS development document (U.S. EPA, September 1983) and includes all data submitted after that proposal. It is identical to the one that appears in the final NSPS development document (U.S. EPA, June 1986).

RAW WASTE CHARACTERISTICS FOR SUBCATEGORY A AND C AND B AND D FACILITIES

Long-term average raw waste BOD_5 concentrations for 27 of 50 direct discharging pharmaceutical plants may be found in Table IV-1. Using these reported values, the Agency was able to compute the required BOD_5 and TSS long-term performance averages which would be in compliance with existing BPT limitations on these pollutants. These averages are also found in Table IV-1. The Agency also developed Option A and Option B performance levels for BOD_5 and TSS based on BCT candidate technology options A and B. The derivation of these performance levels is discussed in detail in sections IV and V of "Development Document for Final New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category," (U.S. EPA, June 1986).

For regulatory purposes, the Agency has grouped the data from subcategory A (fermentation) facilities with the data from subcategory C (chemical synthesis) facilities and the data from subcategory B (extraction) facilities with subcategory D (formulation facilities). Tables IV-2 and IV-3 present the available average data on flow and raw waste BOD_5 and TSS concentrations for A and C and B and D pharmaceutical facilities, respectively. These data along with other information from these facilities have been used in the application of the BCT cost test methodology to four subcategories of the pharmaceutical

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manufacturing point source category. This application is discussed in the remaining sections of this document.

TABLE IV-1

RAW WASTE AND FINAL EFFLUENT CHARACTERISTICS OF DIRECT DISCHARGING PHARMACEUTICAL PLANTS

Plant	Subcategory	Treatment	Flow (MGD)	R.W. BOD_5 (mg/l)	R.W. TSS (mg/l)	LTA BPT BOD_5(mg/l)	LTA BPT TSS(mg/l)	LTA Eff. BOD_5(mg/l)	LTA Eff. TSS(mg/l)
11111*	C	4	0.042	2733.1	-	273.3	464.6	164.5	385.0
12001	D	1	0.140	-	-	-	-	21.0	-
12014	B	1	0.387	-	-	-	-	-	-
12015	D	1	0.101	232.6	124.3	23.3	39.6	9.7	10.8
12022	A,C	1	1.448	2141.6	-	214.2	364.1	110.4	84.8
12026	C	1	0.161	3670.0	87.9	367.0	623.9	108.1	283.7
12036	A,D†	1	1.092	1570.8	1059.1	157.1	267.1	33.0	78.1
12038	A,B,C,D	1	8.316	662.0	-	66.2	112.5	28.3	17.2
12053	D	2	0.019	768.0	560.0	76.8	130.6	5.9	6.8
12073	C	0	0.015	-	-	-	-	-	-
12085	D	1	0.001	-	-	-	-	32.2	29.6
12089	B,D	1	0.350	-	-	-	-	13.0	13.0
12095	C,D	3	0.174	-	133.0	-	-	-	6.2
12097	C,D	1,3	0.064	1577.3	-	157.7	268.1	49.4	18.1
12098	D	1	0.006	-	-	-	-	409.9	392.1
12104	D	2	1.800	-	-	-	-	-	-
12117	B,D	1	0.101	35.2	-	15.0	25.5	1.9	16.0
12119	A,D	1	0.064	-	-	-	-	7.3	70.2
12132	A,C	1	1.04	2916.0	-	291.6	495.7	68.6	452.9
12160	D	2	0.029	490.2	1615.2	49.0	83.3	166.9	115.4
12161	A,C,D††	2	1.700	1463.8	658.8	146.4	248.8	21.5	33.2
12187	C	1	1.065	-	-	-	-	707.3	60.5
12205	D	2	0.036	-	-	-	-	60.0	40.0
12236*	C	1	1.007	1362.0	-	136.2	231.5	155.6	108.3
12248	D	1	0.110	294.4	-	29.4	50.0	26.0	60.4
12256	A,B,C,D	3	****	****	****	****	****	****	****
12283	D	1	0.025	-	-	-	-	35.0	50.0
12287	D	1	0.430	-	-	-	-	-	13.0
12294	C,D	2	0.118	1584.3	-	158.4	269.3	44.7	59.2
12298	D	1	0.007	-	-	-	-	15.0	26.0
12307	D	1	0.010	-	-	-	-	16.0	17.1

TABLE IV-1 (Continued)

Plant	Subcategory	Treatment	Flow (MGD)	R.W. BOD_5 (mg/l)	R.W. TSS (mg/l)	LTA BPT BOD_5(mg/l)	LTA BPT TSS(mg/l)	LTA Eff. BOD_5(mg/l)	LTA Eff. TSS(mg/l)
12308	D	1	0.032	130.0	67.0	15.0	25.5	-	-
12317	D	2	0.740	1003.7	41.4	100.4	170.7	7.9	9.8
12338	D	2	0.004	200.0	200.0	20.0	34.0	30.0	30.0
12406	C	3	0.994	-	420.0	-	-	-	10.0
12459	D	1	0.049	69.5	58.6	15	25.5	3.8	16.7
12462	A	1	0.170	1855.6	1400.1	185.6	315.5	517.0	1373.9
12463	B,D	1	0.056	102.0	-	15	25.5	5.7	9.6
12471	B	1	-	-	-	-	-	-	-
20037	D	1	0.037	-	-	-	-	20.0	47.0
20165	B,C	1	0.004	123.0	-	15.0	25.5	25.0	16.0
20201	D	1	0.002	-	-	-	-	6.0	-
20246	C	2,3	1.590	-	-	-	-	13.0	33.0
20257	C	1	0.107	484.0	-	48.4	82.3	143.0	74.0
20298	C	1	0.001	-	-	-	-	-	-
20319	D	1,3	0.052	-	-	-	-	15.0	8.5
20370	B,C	1	0.014	-	-	-	-	-	-
33333**	C	1,3	0.124	3115.2	725.7	311.5	529.6	121.0	212.0
44444***	D	2,3	0.016	333.0	270.0	33.3	56.6	3.0	30.0
55555	C	1	0.122	1454.4	410.8	145.4	247.2	19.5	86.6

Treatment Codes

0 = No Treatment Reported
1 = Biological Treatment
2 = Biological Treatment + Effluent Filtration
3 = Physical Chemical Treatment
4 = Other

Abbreviations and Notations

R.W. = Raw Waste
LTA = Long-Term Average
* = Return activated sludge in influent
** = Data reported covers less than 6 months period, data measured after incinerator
*** = Data reported covers less than 12 months period
**** = Plant data submitted but it was not possible to determine flow and loadings from these data
† = D subcategory operations contribute 2 percent of the total hydraulic load and 0.1 percent of the total BOD load
†† = D subcategory operations contribute approximately 2 percent of total process flow
- = Data not available

TABLE IV-2

AVERAGE RAW WASTE CHARACTERISTICS OF SUBCATEGORY A AND C PLANTS

Plant	Subcategory	Raw Waste Characteristics Flow (MGD)	BOD_5 (mg/l)	TSS (mg/l)
11111	C	0.042	2,733	NA
12022	A,C	1.448	2,142	NA
12036	A,C,D†	1.092	1,571	1,059
12073	C	0.015	NA	NA
12132	A,C	1.04	2,916	NA
12161	A,C,D**	1.700	1,464	659
12187	C	1.065	NA	NA
12406	C	0.994	NA	420
12462	A	0.170	1,856	1,400
20246	C	1.590	NA	NA
20257	C	0.107	484	NA
20298	C	0.0005	NA	NA
55555	C	0.1215	1,454	411
Average		0.722	1,922*	731*

N.A. = Not available

* Flow-weighted average
† Subcategory D supplies 2.0 percent hydraulic load and 0.1 percent of BOD load
** Subcategory D is less than 2 percent of production

$$\text{Flow Weighted Average Inf. BOD} = \frac{(\text{Flow} \times \text{Inf. BOD})}{\text{Flow}} = 1{,}922 \text{ mg/L}$$

$$\text{Flow Weighted Average Inf. TSS} = \frac{(\text{Flow} \times \text{Inf. TSS})}{\text{Flow}} = 731 \text{ mg/L}$$

TABLE IV-3

AVERAGE RAW WASTE CHARACTERISITCS OF SUBCATEGORY B AND D PLANTS
EMPLOYING BIOLOGICAL TREATMENT

Plant	Subcategory	Raw Waste Characteristics Flow (MGD)	BOD_5 (mg/l)	TSS (mg/l)
12001	D	0.140	N.A.	N.A.
12014	B	0.387	N.A.	N.A.
12015	D	0.101	233	124
12053	D	0.0185	768	560
12085	D	0.0008	N.A.	N.A.
12089	B,D	0.350	N.A.	N.A.
12098	D	0.006	N.A.	N.A.
12104	D	1.800	N.A.	N.A.
12117	B	0.101	35	N.A.
12160	D	0.029	490	1,615
12205	D	0.036	N.A.	N.A.
12248	D	0.110	294	N.A.
12283	D	0.025	N.A.	N.A.
12287	D	0.430	N.A.	N.A.
12298	D	0.007	N.A.	N.A.
12307	D	0.010	N.A.	N.A.
12308	D	0.032	130	67
12317*	D	0.740	N.A.	41
12338	D	0.004	200	200
12459	D	0.049	70	59
12463	B,D	0.056	102	N.A.
12471	B	N.A.	N.A.	N.A.
20037	D	0.037	N.A.	N.A.
20201	D	0.002	N.A.	N.A.
20319	D	0.052	N.A.	N.A.
44444	D	0.016	333	270
Average		0.182	208**	111**

N.A. = Not available
* BOD atypical of other B/D production therefore not used
** Flow-weighted average

TABLE IV-4

AVERAGE PLANT RAW WASTE CHARACTERISTICS

	Raw Waste Characteristics (mg/l)	
	BOD_5	TSS
Subcategory A and C Plant Group	1922	731
Subcategory B and D Plant Group	208	111

SECTION V

DEVELOPMENT OF CONTROL AND TREATMENT OPTIONS

INTRODUCTION

EPA considered two technology options for BCT to control BOD5 and TSS discharges from existing direct discharging pharmaceutical plants. These options were developed after an analysis of all the available data on the operation of biological treatment systems by pharmaceutical manufacturing plants. Both options entail more stringent control of BOD5 and TSS discharges than is required by existing BPT regulations.

CONTROL AND TREATMENT OPTIONS

The two options that have been developed for consideration as the basis of BCT effluent limitations are as follows.

BCT Option A

Promulgate BCT concentration-based limitations controlling BOD5 and TSS based on the performance of the best plants employing advanced biological treatment. BCT limitations for subcategory A (fermentation) plants would be identical to those for subcategory C (chemical synthesis) plants. BCT limitations for subcategory B (extraction) plants would be identical to those for subcategory D (formulation) plants.

Tables V-1 and V-2 present the long-term average final effluent BOD5 and TSS concentrations discharged from best performing A and C and B and D subcategory plants having advanced biological treatment in-place. Also presented in these tables are the numbers of observations used to compute the pollutant averages and the lognormal means of the pollutant distributions. The Agency, in response to public comments, has decided not to use observation-weighted performance averages. Instead, the Agency will use the lognormal means of the pollutant value distributions as the performance averages. The Agency believes that since the pollutant value distributions of the best performing A and C and B and D plants are essentially lognormal in nature, the truest estimate of the mean of each plant's pollutant distribution is the mean of the lognormal distribution. In all cases these means differ only slightly from the arithemetic means. As a result, the long-term Option A performance averages for subcategories A and C are 47.0 and 68.8 mg/l for BOD5 and TSS, respectively.

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BCT Option B

Develop BCT concentration-based limitations controlling BOD_5 and TSS based on the performance of the best plants employing advanced biological treatment in combination with effluent filtration. This option is identical to the technology option which was the basis for the proposed and final (see Section V "Development Document for Final New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category"; U.S. EPA, June, 1986). Two sets of limitations would apply, one set for subcategory A and subcategory C facilities and one set for subcategory B and subcategory D facilities.

Table V-3 presents the long-term average BOD_5 and TSS concentrations achieved after advanced biological treatment and after advanced biological treatment and effluent filtration by plant 12161. Table V-4 presents the long-term average BOD_5 and TSS concentrations achieved by two subcategory D plants with advanced biological treatment and effluent filtration in-place. Also included in these tables are the number of observations used in computing the arithmetic average and the lognormal mean of each pollutant distribution. The data summaries in both tables indicate that little or no removal of BOD_5 is achieved by filtration technology. However, it is apparent that a removal of about 50 percent of the TSS remaining after advanced biological treatment is achieved by filtration by both A and C and B and D best performing plants.

In the case of the A and C subcategory, the Agency has the choice of either setting the Option B BOD_5 and TSS performance average equal to those achieved by plant 12161, the only A and C plant with advanced biological treatment and effluent filtration in-place, or of setting the BOD_5 standard equal to the Option A standard (47.0 mg/l) and the TSS standard at half of the Option A standard (34.4 mg/l). EPA selected the latter approach because this approach involves the use of more of the best performers' data. A check of the TSS removal efficiencies through plant 12161's filter at TSS levels in the final effluent of the other three subcategory A and C best performers indicates they can attain the Option B TSS limit 34.4 mg/l with the addition of filtration.

As for B and D subcategory performance averages, EPA has decided to use the average of the means of the lognormal pollutant distributions of two best performing B and D plants with advanced biological treatment and effluent filtration in-place as Option B performance averages. These are 5.9 and 6.3 mg/l, respectively for BOD_5 and TSS.

BPT

If both option A and B fail the BCT cost test, BCT limitations controlling BOD_5 and TSS will be set equal to existing BPT regulations. BPT limitations are based on the application of

biological treatment and require subcategory A and C facilities to achieve not less than 90 percent BOD_5 reduction on an annual average basis (see Federal Register 48 FR 49808) and effluent TSS concentrations equal to 1.7 times the annual average effluent BOD_5 concentration. B and D subcategory facilities are also required to achieve the same effluent reduction except that in no case will a B and/or D facility be required to achieve an annual average BOD_5 concentration of less than 15 mg/l and an annual average concentration of less than 26.5 mg/l.

TABLE V-1

FINAL EFFLUENT CHARACTERISTICS OF BEST PERFORMING SUBCATEGORY A AND C
PHARMACEUTICAL PLANTS EMPLOYING ADVANCED BIOLOGICAL TREATMENT

		Final Effluent BOD_5 (mg/l)			Final Effluent TSS (mg/l)			
Plant	Subcategory	Number of Observations	Arithmetic Mean	Lognormal Mean	Number of Observations	Arithmetic Mean	Lognormal Mean	Time Period
12022	A,C	391	110.4	115.7	394	84.8	88.0	6/1/78-6/30/79
12036	A,D+	366	33.0	33.0	364	78.1	76.2	6/1/78-6/1/79
12161	A,C,D*	339	21.5	21.6	512	33.2	32.6	6/1/78-7/31/80
55555	C	66	19.5	17.6	181	86.6	78.2	1/1/82-12/31/82
Average			46.1	46.975		70.7	68.750	

NSPS Option A Long-Term
Average Effluent Characteristics BOD_5 = 46.975 mg/l TSS = 68.750 mg/l

+Subcategory D supplies 2.0 of the hydraulic load and 0.1 percent of the BOD load.

*About 2 percent of the total wastewater discharger flow results from formulation operations.

TABLE V-2

FINAL EFFLUENT CHARACTERISTICS OF BEST PERFORMING SUBCATEGORY B AND D PHARMACEUTICAL PLANTS EMPLOYING ADVANCED BIOLOGICAL TREATMENT

		Final Effluent BOD_5 (mg/l)			Final Effluent TSS (mg/l)			
Plant	Subcategory	Number of Observations	Arithmetic Mean	Lognormal Mean	Number of Observations	Arithmetic Mean	Lognormal Mean	Time Period
12015	D	46	9.7	9.6	195	10.8	10.6	6/1/78-6/29/79
12117	B,D	39	1.9	2.2	51	16.0	17.3	7/6/78-6/28/79
12459	D	51	3.8	4.4	47	16.7	16.2	11/2/78-10/31/79
Average			5.1	5.4		14.5	14.7	

NSPS Option A Long-Term
Average Effluent Characteristics: BOD_5 = 5.4 mg/l TSS = 14.7 mg/l

TABLE V-3

FINAL EFFLUENT CHARACTERISTICS OF PHARMACEUTICAL PLANTS
EMPLOYING ADVANCED BIOLOGICAL TREATMENT AND EFFLUENT FILTRATION

Plant	Subcategory	Final Effluent BOD_5 (mg/l) Number of Observations	Arithmetic Mean	Lognormal Mean	Final Effluent TSS (mg/l) Number of Observations	Arithmetic Mean	Lognormal Mean	Time Period
12053	D	39	5.9	5.9	84	6.8	7.0	2/16/82-2/11/83
12317	D	0	--	--	252	5.9	5.6	1/3/83-12/30/83
Average			5.9	5.9		6.4	6.3	
12161	A, C, D*	380	26.9	26.9	633	20.2	17.9	6/1/81-12/31/83
Average			26.9	26.9		20.2	17.9	

NSPS Option B Long-Term
Average Effluent Concentrations BOD_5 = 5.9 mg/l TSS = 6.3 mg/l
*About two percent of the total wastewater discharge flow results from formulation operations.

SECTION VI

COST, ENERGY AND NON-WATER QUALITY ASPECTS

INTRODUCTION

Previous sections describe the development of candidate options for four subcategories of the pharmaceutical manufacturing category. This section discusses the recently promulgated BCT cost test methodology, the methodology for the development of the various incremental costs, the application of cost test to the options and the results thereof, and the cost, energy, and other non-water quality impacts of the final BCT regulations.

THE BCT COST TEST METHODOLOGY

On October 29, 1982, the Agency proposed a revised methodology for determining the reasonableness of BCT effluent limitations guidelines (see 47 FR 49176). EPA has recently finalized this methodology at 51 FR 24974 on July 9, 1986. The final methodology involves a two part test. The first test or POTW compares the cost per pound for plants within an industrial point source category subcategory for reducing their discharge of conventional pollutants with the cost per pound to POTW for similar conventional pollutant reductions. The benchmark comparison figure specified in the final methodology for this first test was $.43/lb (in 1982 dollars). In order for a BCT candidate option to pass the first cost test, the average category or subcategory cost per pound of conventional pollutant removal to be achieved as a result of upgrading from wastewater treatment technology, which achieves BPT conventional pollutant discharge levels to that which achieves conventional pollutant levels characteristic of the candidate option technology, must be less than this benchmark figure.

The second or industry cost-effectiveness test involves comparing the ratio of the BPT-to-BCT candidate option and the raw waste to BPT cost effectivenesses with a POTW cost effectiveness ratio. The POTW ratio is the ratio of secondary to advanced secondary treatment cost effectivness ($/lb) and the primary to secondary treatment cost effectiveness. The benchmark ratio specified in the final methodology is 1.29. Thus for a candidate option for a specific subcategory to pass this test, the ratio of the BPT-to-BCT candidate option cost effectiveness to that calculated for the raw waste to BPT removal must be less than 1.29.

Conventional pollutants are defined by the Act to include BOD5, TSS, oil and grease, fecal coliform and pH. The pollutants included in calculating the POTW pollutant removal are BOD5 and TSS. These pollutants were also used to calculate the pollutant removal for candidate BCT technology options. Oil and grease and fecal coliform were not included since these conventional

pollutants are not generally a concern in the pharmaceutical manufacturing industry. The pollutant parameter pH is not included in the calculations because control of this pollutant is not measurable as "pounds removed." An acceptable interval for controlling pH is dictated by the particular processes of the candidate technologies. Generally, the acceptable pH interval for BCT will be the same as that for BPT.

The calculation of conventional pollutant removals from raw waste to BPT levels and from BPT to the BCT candidate option levels was performed using long-term average pollutant data. The pollutant data supplied by the plants included for the most part averages of at least one year's worth of individual pollutant observations. The raw waste levels used in the calculations were those supplied by the plants in A/C and B/D subcategory averages. BPT level pollutant levels were calculated as prescribed at 48 FR 49808. Plants which conducted both A/C and B/D subcategory operations, i.e. mixed plants were not part of the analysis because flow data on individual subcategory operations were not available in most cases. However, in the cases of plants 12161 and 12036, it was known that a relatively small amount of subcategory D wastewater along with the A/C wastewater is generated at these plants. The Agency has included these plants in the A/C subcategory for the purpose of the BCT cost test analyses. No comments were received on the inclusion of the plants in the A/C subcategory.

METHODOLOGY FOR DEVELOPMENT OF COSTS

The Agency received a number of comments on the costing methodology used in the development of the proposed BCT limitations (see 47 FR 49538). The Agency responded, in effect, to a number of these comments in a Federal Register notice on March 9, 1984 at 49 FR 8967). The Agency has also received additional comments on the costing methodology used to develop the BPT and BPT-to-BCT costs presented in the record supporting the notice and has responded to them by making additional changes to the cost estimating methodology.

Cost Estimating Criteria

In order to develop annual cost estimates for BPT level treatment and treatment afforded by two candidate BCT options, cost estimating criteria were developed for estimating capital costs and operating and maintenance costs (including energy) costs. The criteria which include labor rates, chemical costs, and the amortization rate on capital costs are found in Table VI-1. EPA's estimates are pre-engineering cost estimates and are expected to have a variability consistent with this type of estimate of about plus or minus 30 percent.

Capital Cost Criteria

All cost presented are in 1982 annual average dollars. Since construction costs escalate, these estimates may be adjusted through the use of appropriate cost indices. The most accepted and widely-used cost index in the engineering field is the Engineering News Record (ENR) construction cost index. The ENR index for cost presented in this document is 3825. Equipment costs were based on supplier quotes, published literature, and engineering experience. Capital costs include allowances for lost production during construction and for additional power facilities as warranted. Costs for engineering and contingencies were based on a percentage of the capital costs of the technology component. The percentage varied from 15 to 25 percent depending on the technology component.

Annual Fixed Charges

The annual fixed charges are the annual costs that are directly related to the construction of pollution abatement facilities. These charges commonly include depreciation of the technology equipment, interest on the capital borrowed for construction and installation of technology equipment, interest on the capital borrowed for construction and installation of technology components, and costs for maintenance materials, spare parts, insurance, and taxes.

The useful life of each structure and mechanical unit varies. Mechanical equipment operating under demanding service conditions may have a useful life of 5 to 10 years whereas a building may have a useful life of 40 to 50 years or more. Interest on the capital expenditures for equipment is the annual charge for financing these expenditures which is accomplished by means of corporate bonds or through conventional lending markets.

In calculating annual fixed charges for capital equipment, EPA used an average rate of 22 percent of total capital costs. The annual fixed charge includes costs for interest, depreciation, and capital equipment expenses discussed above. EPA realizes that these charges may vary depending on availability of financing and insurance coverage, the complexity of the technology installed, the required spare parts inventory and the type of maintenance materials required. The Agency has received no adverse comments on the use of 22 percent as its annual fixed charge rate or capital recovery rate.

In calculating total annual costs, EPA included costs for energy, labor for operation and maintenance of equipment, and chemicals. Energy costs were based on an average national electric cost of $0.0495/kwh. This figure is the average retail electric for industrial users from privately owned utilities whose electric operating revenues were $100 million dollars in 1982. The average nonsupervisory labor rate was estimated to be $10.18 per hour in 1982. Average total benefits for the year 1982 were

estimated to be 34 percent of wages. Although no industry-wide data concerning supervisory costs were available, the control and treatment technology options under consideration were anticipated to require only minimal supervisory labor. A supervisory labor and benefits cost of 45 percent of the labor rate was assumed resulting in a total labor rate of $14.76. Chemical costs were based on quotes from chemical suppliers and chemical marketing reports. The chemicals utilized by the technologies under consideration include alum, various polymers, phosphoric acid, sulfuric acid, anhydrous ammonia, and sodium hydroxide.

Revisions Made to the Cost Development Methodology Since Proposal

Since proposal, the Agency has made a number of changes in the BPT and BCT candidate option treatment systems proposed for pharmaceutical manufacturing plants. Initially, the Agency returned to the original subcategorization used in developing BPT limitations (see 48 FR 49808). Thereafter, the Agency identified a new candidate technology option for BCT which was advanced biological treatment plus effluent filtration (Option B) at 49 FR 8697. As a result, two sets of technology options were considered as the basis of BCT for the A and C and B and D subcategories. EPA has made a number of changes in the BPT and BCT candidate Option A and B model treatment systems which have resulted in different BPT and BPT-to-Option A and B cost estimates. These changes have been made in response to public comment and as a consequence of new information and data having been received by the Agency. The changes made in the model treatment system concern the following: an equalization basin, a trickling filter and associated clarifier; biological kinetics; secondary clarifier overflow rates; biological system staging; chlorination costs; and filtration technology (Option B). A discussion of each change along with the rationale for it is presented below.

The changes in BPT and option A and B cost estimates for model treatment systems are also reflected in individual plant cost estimates for achieving BPT limitations and candidate option limitations. The cost changes for individual plants depend on the individual plant circumstances (i.e., raw waste levels and flow) as well as in the methodology changes and, as a result, the individual plant cost changes may be greater or less than those estimated for the model treatment plants. A discussion of the effect of the changes in costing methodology on the individual model BPT, Option A, and Option B plants costs may be found in Section VI of the "Development Document for Final New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category."

Equalization, Trickling Filter, and Chlorination

After a review of the various subcategory treatment trains which are found in "Development Document for Interim Final Effluent Limitations Guidelines and Proposed New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category," (U.S. EPA, December 1976), and the requirements of the final BPT regulations (see 48 FR 49808), the Agency decided that changes in these model treatment trains may be necessary to ensure that they include only those technology elements needed to comply with the promulgated BPT regulations. The Agency agrees with the commenters that the model BPT technology appears to include more technology and more costs than are required to meet the BPT limits. The model BPT biological treatment (referred to by the commenters) is based on equalization, primary clarification, aerated activated sludge treatment followed by secondary clarification, neutralization and effluent chlorination. In the case of the model A and C plants, the Agency concluded that it was not necessary for A and C model plants to have a trickling filter and associated clarifier in its treatment configuration to comply with BPT. All existing A and C plants who comply with BPT do not employ a trickling filter and associated clarifier to do so. At proposal, the Agency included capital and annual costs for chlorination in its model plant cost estimates. Since the purpose of chlorination after biological treatment is to control fecal coliform and no standards for the control of fecal coliform are being promulgated, the Agency has deleted chlorination capital and annual costs from its A and C and B and D model treatment plant costs.

Biological Kinetics

At proposal, the sizes (volumes) of the aeration basins were determined using the Grau equation and assuming a biological k-rate factor of 1.0 day^{-1} for all facilities. In response to the proposal comments, the Agency re-analyzed new and existing k-rate data and developed a linear regression relationship between raw waste BOD_5 and k-rates which allowed the use of plant specific factors to be used in estimating the costs of aeration basins. (See 49 FR 8697). After commenters pointed out that it may be inappropriate to combine k-rate data for all subcategories as was done to develop the linear relationship exists for each subcategory, the Agency has decided to use plant specific k-rate data when available, and use subcategory average k-rates when plant specific data are not available.

The subcategory average biological k-rate used to size the BPT (first stage) aeration basins for model A and C plants was 3.6 day^{-1} while the average rate constant used to size the second stage (option A and B) aeration basins was of model B and D plants. The 0.155 day^{-1} is the second stage rate constant calculated for the only A and C plant with a second stage biological system (plant 12161). The 3.6 day^{-1} and 2.0 day^{-1} rate constants represent average rate constant for

existing A and C and B and D plants achieving BPT, respectively.

In the case of the subcategory B and D BPT plants, the Agency used a minimum detention time of eight hours to size the BPT aeration basins. The Agency believes that a minimum of eight hours of detention time is needed to ensure the completeness of biological oxidation.

Biological System Staging

At proposal, the Agency employed a single stage biological treatment system for both A and C and B and D BPT and BCT option A and B model treatment systems. The biological oxidation of the wastewater was to be accomplished using one set of aeration basins and a secondary clarifier. After reviewing the public comments, the Agency concluded that a two stage system involving two sets of aeration basins and secondary clarifiers would be more appropriate for a BCT option A and B for a A/C plant. This conclusion was reached after reviewing data submitted by A and C plant (plant 12161) which operates with a two stage biological system. In the case of BCT option A and B for B/D plants, the Agency believes, however, that double staging is not appropriate in view of the relatively small amount of BOD_5 removal required from raw waste to BCT option A and B conventional pollutant levels.

Secondary Clarifier Overflow Rates

At proposal, the overflow rates of the secondary clarifiers in the BPT treatment system for the A and C and B and D plants were both 600 gal/sq. ft. as per the design criteria in the 1976 BPT development document. Information presented in public comments as well as available design data from existing plants indicate that a secondary clarifier overflow rate of 400 gal/sq. ft. for the BPT secondary clarifier of both A and C and B and D model plants would be more consistent with the settling characteristics of the suspended solids in pharmaceutical wastewater after activated sludge treatment. Indeed, the average secondary clarifier overflow rates are in the 300 to 500 gal/sq. ft. for most A and C and B and D plants. In choosing, the 400 gal/sq. ft. overflow rate, the Agency essentially agrees with the public commenters. For the overflow rate of the second stage secondary clarifier in the A and C BCT model treatment system, the Agency used an overflow rate of 250 gal/sq. ft. This design rate is consistent with the available pharmaceutical plant data on second stage secondary clarifiers.

Filtration Technology Costs

Comments on the proposed rulemaking indicated that the filtration cost curves underestimated capital and operating costs associated with the installation of multimedia effluent filtration based on

information received from existing facilities employing filtration technology. As a result, EPA based its cost estimates for filtration on a refinement of the Leather Tanning Industry filtration cost curves for gravity units (see Leather Tanning Public Record Section 3-i Volume 2).

Costs and Conventional Pollutant Removals

EPA estimated BPT and BCT candidate option A and B total capital and annual costs for 14 A/C subcategory plants and 25 B/D subcategory plants. The cost estimating criteria used are found in Table VI-1 while the treatment system design bases are found in Tables VI-2 through VI-5. The estimated total capital and annual costs of achieving BPT conventional pollutant discharge levels from raw waste levels for A/C and B/D subcategory plants are found in Tables VI-5 and VI-8, respectively. Also found in these tables are the annual average removals of BOD_5 and TSS achieved in upgrading from raw waste to a BPT level of treatment. Tables VI-6 and VI-9 provide analogous costs and removals for treatment upgrading from BPT to BCT option A levels by A/C and B/D subcategory plants, respectively, while tables VI-7 and VI-9 provide analogous costs and removals for treatment upgrading from BPT to option B levels by A/C and B/D subcategory plants, respectively.

APPLICATION OF THE BCT COST TEST METHODOLOGY

The Agency applied the BCT cost test methodology described earlier in this section to two candidate BCT options for four subcategories of the pharmaceutical industry. For purposes of the BCT cost test, one set of BCT candidate options was applied to the A and C subcategories and one set to the B and D subcategories. The options were identified and discussed in the previous section and in section V of "Development Document for Final New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category." The results of the application of the POTW and Industry Cost Effectiveness tests to candidate options A and B in the A/C and B/D subcategories may be found in Table VI-11. The Agency obtained these results by summing the various incremental (raw waste to BPT and BPT to candidate option) costs and removals found in Tables VI-6 through VI-10.

The results in Table VI-11 indicate that both candidate options fail both cost tests in four subcategories of the pharmaceutical manufacturing point source category. Consequently, BCT limitations for each subcategory are set equal to the BPT limitations.

COST, ENERGY, AND NON-WATER QUALITY IMPACTS

Since final BOD_5 and TSS BCT limitations for four subcategories of the pharmaceutical manufacturing point source category are being set equal to existing BPT limitations on these pollutants, there are no cost, energy, and non-water quality impacts associated with the final BCT limitations.

TABLE VI-1

COST ESTIMATING CRITERIA[1]

1.	Capital costs are expressed as 1982 annual average dollars:		
	ENR = 3825		
2.	Annual fixed (amortized) costs are 22% of capital expenditures		
3.	Energy	Electrical	$0.0495/kwh
4.	Operation and Maintenance:		
	Labor:	General	$14.76/hr
		Solids disposal	$11.41/hr
	Chemicals:	polymer	$ 6.06/kg
		85% phosphoric acid	$ 0.63/kg
		anhydrous ammonia	$220 /kkg dry basis
		100% sulfuric acid	$ 83.6 /kkg
		hydrated lime	$ 46.8 /kkg

[1] Sources of cost data:

Employment and Earnings, U.S. Bureau of the Census, April 1978.

Employment Benefits 1977, Chamber of Commerce of the USA, April 1978.

Energy User News, Vol. 3, No. 32, August 7, 1978.

Engineering News Record, March 23, 1978.

Monthly Energy Review, U.S. Department of Energy, January 1984.

Municipal Sludge Landfills, EPA-625/1-78-010, U.S. Environmental Protection Agency, Process Design Manual, October 1978.

Chemical Marketing Reporter, November 6, 1978.

TABLE VI-2

DESIGN BASIS OF THE TREATMENT SYSTEMS
EXPECTED TO BE EMPLOYED AT PHARMACEUTICAL INDUSTRY
DIRECT DISCHARGERS TO MEET BPT EFFLUENT LEVELS

Wastewater Pumping

Design flow:	1.5 x annual average flow
Basis for power cost:	12m (40 ft) total dynamic head, 70% efficient

Flow Equalization

Detention time:	12 hrs in concrete basin for Subcategory A-C plants 48 hrs in concrete basin for Subcategory B-D plants
Aerator/Mixer Hp:	0.01 hg/m^3 (40 hp/mg)

Diversion Basin (Subcategory A-C only)

Detention time:	48 hours

Neutralization (Subcategory A-C only)

Detention time:	20 minutes
Chemical dosage:	lime = 0.3 kg/m^3 (1.1 ton/mg)

Primary Clarification (Subcategory A-C only)

Overflow rate:	24 $m^3/d/m^2$ (600 gpd/ft^2)
Sidewater depth:	4 m (12 ft)

Activated Sludge Basin

Number of basins:	2
Basin volume:	Use larger value determined from the k-rate equation presented below or an eight-hour minimum detention.

$$k = \frac{So\ (So - Se)}{x\ t\ Se}$$

where Se = effluent BOD (dissolved), mg/l
So = influent BOD (dissolved), mg/l
x = mixed liquor volatile suspended solids, mg/l
t = aeration time, days
k = BOD removal rate coefficient, $days^{-1}$
3.6 for Subcategory A-C plants (Subcategory Average)
2.0 for Subcategory B-D plants (Subcategory Average)

TABLE VI-2 (continued)

DESIGN BASIS OF THE TREATMENT SYSTEMS
EXPECTED TO BE EMPLOYED AT PHARMACEUTICAL INDUSTRY
DIRECT DISCHARGERS TO MEET BPT EFFLUENT LEVELS

Activated Sludge Basin (continued)

Nutrient Feed:	BOD applied: N:P = 100:5:1
Aeration design requirements:	
	O_2 required = 1 kg O_2/kg BODr (1 lb O_2/lb BODr)
	O_2 supplied = 16.3 kg O_2/hp-day (36 lb O_2/hp-day)
	Safety Factor = 1.5
Mixing requirement:	0.03 hp/m^3 (100 hg/mg)

Secondary Clarification

Overflow rate:	16 $m^3/d/m^2$ (400 gpd/ft^2)
Sidewater depth:	4 m (12 ft)

Gravity Sludge Thickener (Subcategory A-C only)

Loading rate:	29 kg/m^2/day (6 lbs/ft^2/day)

Aerobic Digester

Detention time:	20 days

Sludge Storage Tank

Provides storage for 3 days of sludge generation.

Solids Dewatering

Type:	Vacuum filter press
Loading:	20 kg/hr/m^2 (4 lb/hr/ft^2) - Subcategory A-C
	10 kg/hr/m^2 (2 lb/hr/ft^2) - Subcategory B-D
Chemical dosage:	4 kg polymer/kkg solids (8 lb/t solids)

Polishing Ponds (Subcategory A-C only):

Detention Time:	2 days
Solids removal:	Pumping from multiple bottom draw-offs

TABLE VI-2 (continued)

DESIGN BASIS OF THE TREATMENT SYSTEMS
EXPECTED TO BE EMPLOYED AT PHARMACEUTICAL INDUSTRY
DIRECT DISCHARGES TO MEET BPT EFFLUENT LEVELS

Primary/Biological Sludge Transportation	
Haul distance:	16 km (10 miles)
Sludge content:	primary and biological sludge at 30 percent solids (w/w)
Primary/Biological Sludge Landfill	
Sludge content:	primary and biological sludge at 30 pecent solids (w/w)
Landfill design:	normal landfill compaction and covering techniques

TABLE VI-3

DESIGN BASIS OF THE TREATMENT ELEMENTS TO BE ADDED
TO BPT TREATMENT SYSTEMS TO MEET BCT OPTION A EFFLUENT LEVELS

Wastewater Pumping

Design flow:	1.5 x annual average flow
Basis for power cost:	12m (40 ft) total dynamic head, 70% efficient

Activated Sludge Basin

Number of basins:	2
Basin of volume:	Subcategory A-C costs are based on the addition of a second-stage basin. Subcategory B-D costs are based on an enlarged first-stage basin.

$$k = \frac{So\ (So - Se)}{x_v\ t\ Se}$$

where Se = effluent BOD (dissolved), mg/l
So = influent BOD (dissolved), mg/l
x = mixed liquor volatile suspended solids, mg/l
t = aeration time, days
k = BOD removal rate coefficient, $days^{-1}$
Subcategory A-C First-stage average
$k = 3.6\ days^{-1}$
Second-stage average
$k = 0.155\ days^{-1}$
Subcategory B-D Single-stage average
$k = 2.0\ days^{-1}$

Nutrient Feed: BOD applied:N:P: = 100:5:1

Aeration design requirements:

O_2 required = 1 kg O_2/kg BODr (1 lb O_2/lb BODr)
O_2 supplied = 16.3 kg 1_2/hp-day (36 lb O_2/hp-day)
Safety Factor = 1.5

Mixing requirements: 0.03 hp/m^3 (100 hp/mg)

TABLE VI-3 (continued)

DESIGN BASIS OF THE TREATMENT ELEMENTS TO BE ADDED
TO BPT TREATMENT SYSTEMS TO MEET BCT OPTION A EFFLUENT LEVELS

Activated Sludge Basin (continued)

First-Stage Clarification (Subcategory B-D only)

Overflow rate:	10 $m^3/d/m^2$ (250 gpd/ft^2)
Sidewater depth:	4 m (12 ft)

Second-Stage Clarification (Subcategory A-C only)

Overflow rate:	10$m^3/d/m^2$ (250 gpd/ft^2)
Sidewater dept:	4 m (12 ft)

Sludge Handling Costs were included to provide the incremental sludge thickeners and aerobic digestion capacity as necessary, based on the BPT design criteria.

Sludge Disposal Costs were included for the necessary additional O&M and energy costs incurred to dewater the BCT incremental solids on the BPT vacuum filter. Costs were included to dispose the incremental BCT solids in the same manner as BPT solids.

TABLE VI-4

DESIGN BASIS OF THE FILTRATION SYSTEM TO BE ADDED TO THE BCT OPTION A TREATMENT SYSTEM TO MEET BCT OPTION B EFFLUENT LEVELS

Filtration:

Type:	Multimedia	
Hydraulic Loading:	0.102 $m^3/min/m^2$	(2.5 gpm/ft^2) - Subcategory A-C
	0.061 $m^3/min/m^2$	(1.5 gpm/ft^2) - Subcategory B-D

TABLE VI-5

SUBCATEGORY AC

RAW WASTE LOAD TO BPT INCREMENT OF TREATMENT

COSTS AND REMOVALS

Plant	Capital Cost ($1000)	Total Annual ($1000/yr)	Annual Average removal (1000 lb/yr) BOD	TSS	Total	BPT ($/lb)
12036A	7738.7	2741.7	4700.026	2632.5	7332.526	.37
12462A	2537.4	897.0	864.427	561.215	1425.642	.63
11111C	1089.2	417.1	314.478	34.059	348.537	1.20
12073C	459.3	176.2	78.985	18.459	97.444	1.81
12187C	7421.9	2787.8	5607.954	1310.597	6918.551	.40
12236C	6989.2	2621.3	5160.37	1205.996	6366.366	.41
12406C	6472.7	2447.0	5234.09	282.189	5516.279	.44
20246C	9964.7	3775.5	8372.438	1956.667	10329.105	.37
20257C	1423.9	517.5	141.883	211.3	353.183	1.47
20298C	88.2	29.6	2.633	.615	3.248	9.11
33333C	1918.9	702.9	684.539	159.979	844.518	.83
55555C	1590.1	585.0	485.988	0	485.988	1.20
12022AC	9663.3	3667.3	8497.466	1617.066	10114.532	.36
12132AC	8454.6	3230.4	8308.493	744.864	9053.357	.36
12161AC	9071.6	3448.2	6818.54	2122.359	8940.899	.39
Totals	74883.7	28044.5			68130.175	.412

All costs are in 1982 annual average dollars, ENR=3825

TABLE VI-6

SUBCATEGORY AC

BPT TO BCT OPTION A INCREMENT OF TREATMENT

COSTS AND REMOVALS

Plant	Capital Cost ($1000)	Total Annual ($1000/yr)	Annual Average Removal (1000 lb/yr) BOD	TSS	Total	Cost Effectiveness Option A ($/lb)	Industry Comparison BCT/BPT
12036A	2847.8	953.3	366.073	659.247	1025.32	.93	2.49
12462A	987.6	344.7	71.738	127.703	199.441	1.73	2.75
11111C	531.9	206.8	28.936	50.612	79.548	2.60	2.17
12073C	197.9	68.1	6.631	11.78	18.411	3.70	2.05
12187C	3139.2	1069.6	470.815	836.395	1307.21	.82	2.03
12236C	2971.2	1014.5	433.238	769.64	1202.878	.84	2.05
12406C	3000.5	1026.8	439.427	780.635	1220.062	.84	1.90
20246C	4083.9	1383.4	702.906	1248.702	1951.608	.71	1.94
20257C*							
20298C	51.8	17.1	.221	.393	.614	27.85	3.06
33333C	858.5	308.0	57.47	102.095	159.565	1.93	2.32
55555C	720.6	260.3	36.553	66.265	102.818	2.53	2.10
12022AC	4104.9	1405.5	737.104	1302.037	2039.141	.69	1.90
12132AC	4064.2	1425.7	774.449	1351.729	2126.178	.67	1.88
12161AC	4687.3	1547.1	514.521	932.167	1446.688	1.07	2.77
Totals	32247.3	11030.9			12879.482	.856	2.081

All costs are in 1982 annual average dollars, ENR = 3825.

*Since BPT levels of BOD_5 and TSS for this plant are lower than the BCT candidate option A levels, no costs or removals have been estimated.

TABLE VI-7

SUBCATEGORY AC

BPT TO BCT OPTION B INCREMENT OF TREATMENT

COSTS AND REMOVALS

Plant	Capital Cost ($1000)	Total Annual ($1000/yr)	Annual Average Removal (1000 lb/yr)			Cost Effectiveness	
			BOD	TSS	Total	Option B ($/lb)	Industry Comparison BCT/BPT
12036A	3590.3	1154.3	366.073	773.515	1139.588	1.01	2.71
12462A	1340.1	438.9	71.738	145.492	217.23	2.02	3.21
11111C	732.9	261.8	28.936	55.006	83.942	3.12	2.61
12073C	332.1	105.0	6.631	13.35	19.981	5.25	2.91
12187C	3866.1	1266.4	470.815	947.838	1418.653	.89	2.22
12236C	3676.1	1204.9	433.238	872.189	1305.427	.92	2.24
12406C	3707.9	1218.0	439.427	884.648	1324.075	.92	2.07
20246C	4938.6	1616.9	702.906	1415.081	2117.987	.76	2.09
20257C*							
20298C	83.1	27.2	.221	.445	.666	40.84	4.48
33333C	1173.6	393.3	57.47	115.698	173.168	2.27	2.73
55555C	1030.9	345.3	36.553	79.032	115.585	2.99	2.48
12022AC	4923.2	1627.4	737.104	1453.557	2190.661	.74	2.05
12132AC	4771.1	1615.2	774.449	1460.556	2235.005	.72	2.03
12161AC	5579.7	1792.5	514.521	1110.057	1624.578	1.10	2.86
Totals	39745.7	13067.1			13966.546	.936	2.273

All costs are in 1982 annual average dollars, ENR = 3825.

*Since BPT levels of BOD_5 and TSS for this plant are lower than the BCT candidate option B levels, no costs or removals have been estimated.

TABLE VI-8

SUBCATEGORY BD

RAW WASTE LOAD TO BPT INCREMENT OF TREATMENT

COSTS AND REMOVALS

Plant	Capital Cost ($1000)	Total Annual ($1000/yr)	Annual Average Removals (1000 lb/yr) BOD	TSS	Total	BPT ($/lb)
12001/D	1163.8	426.0	79.78	32.236	112.016	3.80
12015/D	991.3	374.8	64.428	25.928	90.356	4.15
12053/D	252.1	88.5	38.926	24.184	63.11	1.40
12085/D	79.4	22.2	.456	.184	.64	34.69
12098/D	147.9	43.1	3.146	1.271	4.417	9.76
12104/D	5330.0	1709.2	1025.74	414.46	1440.2	1.19
12160/D	385.0	162.1	39.401	136.849	176.25	.92
12205/D	403.8	118.1	20.515	8.289	28.804	4.10
12248/D	1057.2	396.2	88.239	20.349	108.588	3.65
12283/D	343.6	98.9	14.246	5.756	20.002	4.94
12287/D	2227.0	749.0	245.038	99.01	344.048	2.18
12298/D	158.9	46.7	3.989	1.612	5.601	8.34
12307/D	184.5	54.7	5.699	2.303	8.002	6.84
12308/D	381.3	108.4	11.202	4.043	15.245	7.11
12317/D	4172.0	1436.0	2035.012		2035.012	.71
12338/D	127.8	37.2	2.192	2.021	4.213	8.83
12459/D	570.4	235.3	8.217	5.005	13.222	17.80
20037/D	408.8	119.7	21.085	8.519	29.604	4.04
20201/D	100.7	28.6	1.368	.553	1.921	14.89
20319/D	678.7	276.6	29.632	11.973	41.605	6.65
44444/D	285.8	84.5	14.506	10.328	24.834	3.40
12014/B	2093.4	708.6	320.534	89.109	309.643	2.29
10289/BD	1975.0	672.6	199.449	80.59	280.039	2.40
12117/BD	872.9	330.4	6.141	26.251	32.392	10.20
12463/BD	668.5	271.0	14.831	14.575	29.406	9.22
Totals	25059.8	8598.4			5219.17	1.647

All costs are in 1982 annual average dollars, ENR = 3825.

TABLE VI-9

SUBCATEGORY BD

BPT TO BCT OPTION A INCREMENT OF TREATMENT
COSTS AND REMOVALS

Plant	Capital Cost ($1000)	Total Annual ($1000/yr)	Annual Average Removals (1000 lb yr)			Cost Effectiveness	
			BOD	TSS	Total	Option A ($/lb)	Industry Comparison BCT/BPT
12001/D	327.5	161.9	6.563	8.805	15.368	10.53	2.77
12015/D	280.4	146.1	5.5	7.653	13.153	11.11	2.68
12053/D	79.3	34.6	4.021	6.525	10.546	3.28	2.34
12085/D	11.6	6.0	.038	.05	.088	68.18	1.97
12098/D	36.7	16.3	.259	.347	.606	26.90	2.76
12104/D	1870.8	665.5	84.382	113.204	197.586	3.37	2.84
12160/D	102.4	42.9	3.895	6.129	10.024	4.28	4.65
12205/D	114.7	45.7	1.688	2.264	3.952	11.56	2.82
12248/D	386.9	188.0	8.004	11.765	19.769	9.51	2.61
12283/D	91.1	37.0	1.172	1.572	2.744	13.48	2.73
12287/D	698.3	290.4	20.158	27.043	47.201	6.15	2.83
12298/D	40.4	17.7	.328	.44	.768	23.05	2.76
12307/D	50.8	21.7	.469	.629	1.098	19.76	2.89
12308/D	105.5	41.9	.935	1.052	1.987	21.09	2.97
12317/D	7151.7	2449.0	213.951	351.285	565.236	4.33	6.14
12338/D	28.6	13.1	.178	.235	.413	31.72	3.59
12459/D	140.6	90.2	1.434	1.614	3.048	29.59	1.66
20037/D	116.7	46.4	1.735	2.327	4.062	11.42	2.83
20201/D	18.3	8.8	.113	.151	.264	33.33	2.24
20319/D	169.2	100.9	2.438	3.27	5.708	17.68	2.66
44444/D	69.4	29.3	1.35	2.028	3.378	8.67	2.55
12014/B	650.5	274.4	18.142	24.339	42.481	6.46	2.82
12089/BD	606.9	259.6	16.408	22.012	38.42	6.76	2.81
12117/BD	209.1	113.6	2.947	3.316	6.263	18.14	1.78
12463/BD	113.3	74.3	1.637	1.841	3.478	21.36	2.32
Totals	13470.7	5175.3			997.641	5.188	3.149

All costs are in 1982 annual average dollars, ENR = 3825.

TABLE VI-10

SUBCATEGORY BD

BPT TO BCT OPTION B INCREMENT OF TREATMENT
COSTS AND REMOVALS

Plant	Capital Cost ($1000)	Total Annual ($1000/yr)	Annual Average Removals (1000 lb/yr)			Cost Effectiveness	
			BOD	TSS	Total	Option B ($/lb)	Industry Comparison BCT/BPT
12001/D	700.1	261.0	6.563	12.385	18.948	13.77	3.62
12015/D	612.9	236.6	5.5	10.234	15.734	15.04	3.63
12053/D	249.6	79.6	4.021	6.998	11.019	7.22	5.15
12085/D	64.8	21.8	.038	.071	.109	200.00	5.77
12098/D	144.7	45.8	.259	.488	.747	61.31	6.28
12104/D	2870.1	920.0	84.382	159.231	243.613	3.78	3.18
12160/D	305.2	96.1	3.895	6.88	10.775	8.92	9.70
12205/D	334.5	103.1	1.688	3.185	4.873	21.16	5.16
12248/D	729.2	280.5	8.004	14.566	22.57	12.43	3.41
12283/D	282.0	87.1	1.172	2.212	3.384	25.74	5.21
12287/D	1272.2	439.3	20.158	38.038	58.196	7.55	3.47
12298/D	157.8	49.8	.328	.619	.947	52.59	6.31
12307/D	185.1	57.9	.469	.885	1.354	42.76	6.26
12308/D	315.4	96.7	.935	1.87	2.805	34.47	4.85
12317/D	7858.9	2627.6	213.951	370.203	584.154	4.50	6.37
12338/D	124.4	39.6	.178	.337	.515	76.89	8.71
12459/D	392.3	165.8	1.434	2.869	4.303	38.53	2.17
20037/D	338.4	104.3	1.735	3.273	5.008	20.83	5.15
20201/D	96.3	30.9	.113	.212	.325	95.08	6.39
20319/D	425.0	171.9	2.438	4.6	7.038	24.42	3.67
44444/D	230.4	72.0	1.35	2.435	3.785	19.02	5.59
12014/B	1201.0	417.3	18.142	34.235	52.377	7.97	3.48
12089/BD	1137.3	397.8	16.408	30.962	47.37	8.40	3.50
12117/BD	543.1	209.7	2.947	5.895	8.842	23.72	2.33
12463/BD	379.2	150.8	1.637	3.273	4.91	30.71	3.33
Totals	20949.9	7163			1113.701	6.432	3.904

All costs are in 1982 annual average dollars, ENR = 3825.

TABLE VI-11

SUMMARY OF BCT COST TEST CALCULATIONS
FOR THE PHARMACEUTICAL MANUFACTURING INDUSTRY
(1982 Dollars)

Subcategory (Subpart)	POTW Test[1]	Industry Cost Test[2]
Fermentation (A)		
Option A	$ .86	2.08
Option B	$ .94	2.27
Extraction (B)		
Option A	$5.19	3.15
Option B	$6.43	3.90
Chemical Synthesis (C)		
Option A	$ .86	2.08
Option B	$ .94	2.27
Formulation (D)		
Option A	$5.19	3.15
Option B	$6.43	3.90

1 POTW Test =

$$\frac{\text{total annual cost (BPT->BCT candidate technology) in 1982 dollars}}{\text{annual average removal in lbs candidate technology passes if POTW test } < \frac{\$.43}{\text{lb}} \text{ in 1982 dollars}}$$

2 Industry Cost Test =

$$\frac{\text{total annual cost/lb removed (BPT->BCT candidate technology)}}{\text{total annual cost/lb removed (Raw Waste Load -> BPT)}}$$

Candidate technology passes if industry cost test <1.29

SECTION VII

BEST CONVENTIONAL TECHNOLOGY EFFLUENT LIMITATION GUIDELINES

GENERAL

The basis for best conventional pollutant control technology (BCT) effluent limitation guidelines under section 304 of the Act is best conventional technology. As described in the preceding section, EPA selected the basis for BCT following application of the recently promulgated BCT cost test methodology (see 51 FR 24974).

IDENTIFICATION OF THE TECHNOLOGY BASIS OF FINAL BCT LIMITATIONS

The technology basis selected for control of BOD5 and TSS under BCT is biological treatment (i.e., biological treatment which is the basis of effluent limitation guidelines reflecting the best practicable control technology currently available (BPT)).

FINAL BCT

Table VII-1 presents BCT limitations controlling the conventional pollutants BOD5, TSS, and pH.

RATIONALE FOR THE SELECTION OF BCT CANDIDATE OPTIONS

The Agency developed two technology options which would result in final BCT limitations being more stringent than existing BPT limitations. These technology options were developed after consideration of all the available data concerning wastewater treatment systems in use in the pharmaceutical industry. A description of the plant data supporting these technology options may be found in section V of this document. A discussion of the methodology used to estimate incremental (beyond BPT) costs associated with each of these options may be found in Section VI.

METHODOLOGY USED FOR DEVELOPMENT OF FINAL BCT

As discussed in Section VI, EPA used the recently promulgated BCT cost test methodology to evaluate two candidate technology options for the A/C and B/D subcategories of the pharmaceutical manufacturing industry. Both candidate options failed both the POTW and industry cost tests and, as a result, final BCT limitations on BOD5 and TSS are set equal to existing BPT limitations on these pollutants.

COST OF APPLICATION AND EFFLUENT REDUCTION BENEFITS

Since BCT limitations are being set equal to existing BPT limitations, there are no incremental capital or annual costs or removals associated with these final regulations.

NON-WATER QUALITY ENVIRONMENTAL IMPACTS

Section 304(b) of the Act requires EPA to consider the non-water quality environmental impacts (including energy requirements) of certain regulations. Since final BCT limitations are equal to existing BPT limitations, there are no non-water quality environmental impacts expected as a result of this regulation.

TABLE VII-1

FINAL BCT LIMITATIONS FOR THE
PHARMACEUTICAL MANUFACTURING CATEGORY

Subcategory	BOD_5 30-Day Maximum Average	TSS 30-Day Maximum Average	pH
A	0.10 x long-term average raw waste concentration x 3 (variability factor)	1.7 x BOD_5 30-day maximum average limitation	6.0-9.0 units at all times
B	0.10 x long-term average raw waste concentration x 3 (variability factor) or 45 mg/l, whichever is higher	1.7 x BOD_5 30-day maximum average limitation	6.0-9.0 units at all times
C	0.10 x long-term average raw waste concentration x 3 (variability factor)	1.7 x BOD_5 30-day maximum average limitation	6.0-9.0 units at all times
D	0.10 x long-term average raw waste concentration x 3 (variability factor) or 45 mg/l, whichever is higher	1.7 x BOD_5 30-day maximum average limitation	6.0-9.0 units at all times

SECTION VIII

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5. Gibbons, J. D., Nonparametric Statistical Inference, McGraw-Hill, 1971.

6. Wilks, S. S., Mathematical Statistics, Wiley & Sons, 1963.

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SECTION IX

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